IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** **WAVE 1 CASES**	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' RESPONSE TO DEFENDANTS' MOTION TO LIMIT CERTAIN OPINIONS AND TESTIMONY OF RALPH ZIPPER, M.D.

COMES NOW, the Plaintiffs in the above-styled case, and files their Response to Defendants' *Motion to Exclude Certain Opinions of Ralph Zipper, M.D.*, and shows the following:

INTRODUCTION

Plaintiffs have designated Dr. Ralph Zipper as an expert in this case to offer expert opinion testimony that, among other things, the Prosima and Prolift devices were defectively designed, that as a result of the defects in the design of the Prosima and Prolift products, patients were placed at an unreasonably high risk of severe complications unique to the design of these products, that Defendant Ethicon failed to adequately warn patients and their physicians of the unique complications associated with the Prosima and Prolift and the difficulty treating these mesh-related complications, and that the company failed to adequately test the Prosima and Prolift products before placing them on the market despite the Material Data Sheet that expressly prohibited the use of the Marlex resin in permanently implantable medical devices. In response, the Defendants' have moved to exclude the following opinions of Dr. Zipper's:

I. The Prosima and Prolift devices are defectively designed;

II. There are safer alternative products and procedures;

III. The *Instructions for Use* (IFU) is inadequate;

IV. Ethicon had knowledge of undisclosed risks;

V. Ethicon committed fraud on the FDA.

However, all of these opinions are well within Dr. Zipper's realm of expertise and experience. Notably, similar motions to exclude Dr. Zipper's expert testimony with respect to design defect opinions have been denied. In the Court of Common Pleas in Philadelphia, Judge Arnold New denied Ethicon's motion to exclude Dr. Zipper's design defect opinions, including his opinions concerning mesh degradation and contraction. *See* Exhibit "A". Ethicon renewed its motion to exclude Dr. Zipper at trial. After hearing testimony concerning Dr. Zipper's qualifications and experience, Judge Mark Bernstein again denied Ethicon's motion, finding "[t]he witness is qualified to provide expert opinion testimony in his fields of expertise." *See* Exhibit "B" at 27:7-9.[1]

Dr. Zipper has based all of his opinions in this case on his extensive review of the medical and scientific literature, Ethicon's internal documents, his knowledge, training, education, and experience, including his experience consulting for mesh device manufacturers, such as Defendant Ethicon, and his review of relevant deposition transcripts. Moreover, Dr. Zipper's opinions are based on reliable methods, including the method of differential diagnosis and his thorough review of Ethicon's internal documents and medical and scientific publications – methods he routinely uses in his clinical practice treating patients and in his role as president and COO of medical device manufacturers.

[1] Notably, Judge Bernstein authored the comprehensive commentary on Pennsylvania Evidence.

LEGAL STANDARD

For the sake of brevity and because the Court is fully aware of the legal standards governing the admissibility of expert testimony in the Fourth Circuit, Plaintiffs will not set forth a detailed discussion of the legal standard. It is known and understood that the admissibility of expert testimony is governed by the Federal Rules of Evidence, including but not limited to Rules 702, 403 and 104. *See Bryte v. Am. Household, Inc.*, 429 F.3d 469, 476 (4th Cir. 2005) (federal law governs admissibility of expert testimony). The trial judge acts as a gatekeeper for scientific, technical and other specialized knowledge. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993); *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 141 (1999). As this Court has previously concluded,

> I "need not determine that the proffered expert testimony is irrefutable or certainly correct" — "[a]s with all other admissible evidence, expert testimony is subject to testing by '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" . . . "[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached."

Eghnayem v. Boston Scientific Corp., 57 F. Supp. 3d 658, 669 (S.D.W.Va. 2014).

ARGUMENT

I. Dr. Zipper is qualified to testify on the design of mesh products and the characteristics of polypropylene. His testimony on this subject is reliable and relevant.

As a urogynecologist board certified in Female Pelvic Medicine and Reconstruction, Dr. Zipper is more than qualified to offer opinions concerning the design of mesh devices, and opine on the material characteristics of polypropylene. Dr. Zipper has already been deemed qualified to provide nearly identical opinions in a similar case, and is qualified to testify in the instant case.

This Court has repeatedly and consistently rejected similar *Daubert* challenges made by mesh manufacturers attacking other similarly qualified urogynecologists who offer opinions based on similar methodology as that employed by Dr. Zipper. In *Wilkerson v. Boston Scientific Corp.*, 2015 WL 2087048 (S.D.W.Va. 2015), the Defendants sought to exclude Dr. Bruce Rosenzweig's opinions on the biomaterial properties of polypropylene based on the fact that he has no background in biochemistry and was therefore unqualified "to render opinions that 'deal with polymer science, biochemistry or biomaterials.'" *Id.* at 5. This Court denied that argument stating:

> [A]lthough Dr. Rosenzweig [expert urogynecologist who offered general causation opinions on the properties of polypropylene mesh, body's reaction to mesh, and complications] may not know the precisions of oxidative degradation, Dr. Rosenzweig has demonstrated extensive knowledge of and experience with the process of polypropylene mesh degradation in the body. He has performed "over a thousand pelvic floor surgical procedures," as well as "close to 300 surgeries dealing with complications related to synthetic mesh." And as he explained during his deposition, "I have explanted mesh. I have seen degraded mesh. I've seen hardened, brittled, fragmented mesh upon removal of mesh." Furthermore, Dr. Rosenzweig has read "close to the 2,000 papers that have been generated on midurethral slings." Dr. Rosenzweig's established background and skill in pelvic surgery, polypropylene, and the complications associated with degradation qualify him to opine on the degradation process, even though his knowledge about the precise biochemical interactions involved might not be as extensive as that of others.… Any gaps in Dr. Rosenzweig's knowledge go to his credibility, not his admissibility as an expert.

Id. at 5. As discussed below, Dr. Zipper has as much, if not more "knowledge of and experience with the process of polypropylene mesh degradation" than that of Dr. Rosenzweig.

Since the early part of this century, Dr. Zipper has performed thousands of transvaginal mesh procedures and hundreds of abdominal surgeries utilizing mesh for the treatment of pelvic organ prolapse and stress urinary incontinence. *See* Exhibit "B" at 14:23-15:1. Furthermore, he has explanted over 500 hundred pieces of mesh, including more than 100 pieces of Prolift specifically. Exhibit "C" at 104:21-22. Over the last ten

years, he has trained more than one thousand urologists and gynecologists in the surgical techniques of prolapse and incontinence surgery. *See* Exhibit "D" at 3.

While Dr. Zipper's surgical experience is beyond impressive, he has "spent much of his career commercializing and developing products," and has "expertise in material science" even though he is not a "material scientist." Exhibit "E" at 123:4-10. As stated by the doctor himself, "I have a[n] increased fund of knowledge that someone would consider a level of expertise in materials that I have used and/or tried to commercialize within my field of endeavor." *Id*. at 123:13-16. Furthermore, he has worked with engineers to develop and commercialize "[d]evices for the treatment of urinary incontinence, devices for the treatment of pelvic organ prolapse, devices for the treatment of overactive bladder disease, devices for the treatment of pelvic pain, [and] devices for the treatment of female sexual dysfunction and/or function." Exhibit "D" at 4. When developing these products, Dr. Zipper visits the manufacturer of the materials to be used in the device, and examines the manufacturing process and the materials produced. Exhibit "E" 124:6-125:9. On certain occasions, he reviews the *Material Data Safety Sheet* (MSDS) to see what kind of biocompatibility testing has been performed and looks at the physical properties of the material, e.g., the burst strength and elasticity. *Id.*

In addition to the above, Dr. Zipper necessarily keeps current on literature relevant to his practice, including the "breadth of medical literature that quite consistently demonstrates the material mismatch associated with polypropylene mesh; the concerns of heavier polypropylene meshes compared to the lightweight polypropylene meshes' the concerns over pore size; concerns over the methods that it transgress and transit the obturator foramen in proximity to the obturator canal . . . ." Exhibit "F" at 40:7-14. Over the course of time, Dr. Zipper has read,

"thousands and thousands of articles … that have led to the development of [his] opinion…." Exhibit "C" at 13:18-14:14.

As a private independent consultant, Dr. Zipper has worked closely with engineers to develop devices slings and mesh products for the treatment of stress urinary incontinence and pelvic organ prolapse, many of which were subsequently developed and sold by foreign and U.S. medical device companies. Exhibit "D" at 4. In this same role, he worked extensively to craft instructional materials and marketing materials for prolapse mesh and incontinence products. *See Id.* Dr. Zipper has authored fifteen relevant patent applications and been issued multiple patents relevant to the field of pelvic reconstructive surgery that are published by the United States Patent and Trade Office. *Id*. at 3.

Daubert's focus is whether an expert has the "knowledge, skill, experience, training, or education" to opine on a subject. It does not ask whether a witness has been granted a particular patent or some other credential only tangentially related to the opinion. Dr. Zipper does not need to have a degree in "materials science" or practice exclusively in that field to be qualified to testify on the design of mesh and the characteristics of polypropylene. *See, e.g, Pineda v. Ford Motor Co*., 520 F.3d 237, 244 (3d Cir. 2008) (*citing Holbrook v. Lykes Bros. S.S. Co.*, 80 F.3d 777 (3d Cir. 2003). Dr. Zipper's collective knowledge, skill, experience, and training qualify him to do so.

a. Dr. Zipper's testimony on polypropylene's characteristics is based on his examination of explanted mesh as well as his extensive experience implanting mesh, treating its complications, and explanting mesh when necessary.

Dr. Zipper's methodology in examining mesh samples meets *Daubert*'s standards of reliability. Expert testimony based on personal observation should be considered reliable as long as the expert possesses specialized knowledge on which to base his opinion. *See Daubert*, 509

U.S. at 592-593. During an explant, Dr. Zipper first removes the explanted mesh from the pelvis. Exhibit "E" at 133:5-137:1. He then cleans the material of ingrained fibrous tissue, manipulates it, dissects the mesh for further examination, and compares it side by side to mesh which has not been implanted. *Id*. Based on his extensive education, training, and experience in pelvic prolapse as well as his study of scientific literature, Dr. Zipper is able to determine what changes have occurred in the mesh after implantation. *Id*. Dr. Zipper has previously testified, "the mesh I remove, the physical characteristics suggest or are very indicative of changes in the material properties of the mesh since the time of initial implantation to a more brittle, fragile, less elastic state." Exhibit "F" at 307:22-308:3. Furthermore, in preparing his report he consulted "a tremendous number of documents, an exhausting number of documents aside from my own clinic experience, my years of treating patients, implanting, explanting. . . ." *Id.* at 114:9-14. His observations show that when "mesh comes out it is so altered, it is so shrunken, it is so brittle, it is so contracted that it's almost unrecognizable." *Id*. at 135:11-13. Additionally, he has "studied the contraction and shrinkage of mesh…through a review of the scientific literature, medical literature. And…my own investigation by evaluating the changes taking place in the products that I implant versus the products that I explant." *Id*. at 149:23-150:2. He has also studied the flexibility of mesh before and after implantation. As noted, in his product development role, Dr. Zipper would look at elasticity, tensile strength, and burst of mesh products. *Id*. at 152:9-12.

Dr. Zipper's examinations are informed by his expertise. Dr. Zipper was qualified as an expert on urogynecology and pelvic products long before he ever became involved in litigation. His examinations and dissections of the mesh are reliable because they were done under typical scientific methods by a trained expert. This underlying expertise has been supplemented by his

study of the documents "with great meticulousness." *Id.* at 116:14. Accordingly, Ethicon's motion should be denied.

II. Dr. Zipper's opinion that there are safer alternative products is supported by sufficient facts.

Ethicon's argument that Dr. Zipper has no basis to support his conclusions regarding safety and efficacy of an alternative design is baseless and must be rejected. Ethicon states that Dr. Zipper failed to disclose testing, calculations, engineering analysis, or publications that support his opinion, but this representation is false. Dr. Zipper cites to numerous publications and internal documents demonstrating safer alternatives, including non-mesh procedures, suture procedure and alternative designs using larger pore, lighter weight mesh (e.g., Ultrapro). *See* e.g. Exhibit "D" at 175-178. Furthermore, Dr. Zipper's experience with implanting thousands of various synthetic mesh products, his experience developing synthetic mesh products, and his experience explanting hundreds of mesh devices gives him firsthand knowledge of those products that provide a safer alternative to the Prolift products. Accordingly, Ethicon's motion should be denied.

III. Dr. Zipper is qualified to offer opinions concerning Ethicon's failure to provide adequate instructions for the safe use of the Prosima and Prolift Products, Ethicon's failure to adequately warn physicians and patients of the serious risks associated with the Prosima and Prolift products, and Ethicon's failure to adequately test the products before placing them on the market.

Dr. Zipper has read and is familiar with the Instructions for Use (IFU), the guidance documents concerning labeling requirements for medical devices, sales and marketing materials, and physician training materials for the devices he has used. Exhibit "D" at 4. As a practicing urogynecologist, he keeps current on the peer-reviewed publications concerning mesh devices and associated complications and is keenly familiar with the risks and complications associated

with mesh procedures and devices, including those associated with the Prosima and Prolift products. *Id.*

As a urogynecologist with extensive experience with mesh products, Dr. Zipper is well qualified to offer opinions concerning the IFU, including Ethicon's inadequate and defective instructions for the implantation method described in the Prosima and Prolift IFUs, and Ethicon's failure to adequately warn physicians and patients of the unique risks associated with these products. Dr. Zipper previously testified that he has unique experience regarding the language in the IFU through his design development endeavors and the consulting work he has provided to medical device manufacturers. Exhibit "G" at 240:9-249:17. His opinions with regard to the inadequacy of the IFUs and the components of the IFUs, including the warnings and cautions, as well as the descriptions of the procedures are based upon my years of clinical experience, my knowledge, my training, my review of the peer-reviewed literature, my review of the non-peer-reviewed literature, my consultant work which includes the reviewing of IFUs. *Id.* In reaching his opinion in this case, he used the same type of methods that the manufacturing companies wanted him to apply when giving them recommendations about labeling. *Id.* As such, Dr. Zipper has the expertise to offer opinions concerning the adequacy of Ethicon's IFUs and applied the same reliable methods he uses when consulting with medical device manufacturers concerning the adequacy of warning and instruction in reaching his opinions in this case; therefore, Dr. Zipper should be permitted to offer opinions concerning the adequacy of Ethicon's prosoma and Prolift IFUs in this case.

Even if not considered an expert *per se* in product warnings—which he is—his opinions on the inadequacies of the IFU are still admissible based on his extensive experience as a urogynecologist that is board certified in pelvic reconstruction surgery and who has treated

hundreds of patients having mesh related complications. This Court has previously ruled that an individual proffered as an expert in product warnings need not be an expert *per se* so long as they have extensive experience treating patients with mesh related complications. *See Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 703-704, 719-720 (S.D.W.Va. 2014). Accordingly, Ethicon's motion should be denied.

IV. Plaintiffs will abide by the Court's prior rulings on opinion testimony relating to Ethicon's knowledge, state of mind or alleged bad acts and will not elicit any such testimony from Dr. Zipper.

V. FDA opinion testimony

Plaintiffs recognize the Court's prior rulings on the admissibility of FDA testimony as it relates to the FDA and will adhere to any future rulings with respect thereto in this case. In the event the Court allows such testimony involving FDA and Ethicon's 510K submissions as they relate to the Prosima and Prolift products, and their subsequent clearance by the FDA, Plaintiffs must have the ability to counter such evidence with opinion testimony from Dr. Zipper relating to the "incorrect," "insufficient" and "deceitful" information provided to the FDA to gain rapid clearance for marketing and bypass the PMA process and also to the misbranding of the devices instructions for use. Dr. Zipper is more than qualified to render such opinions given his extensive experience with implanting thousands of synthetic mesh devices, the consulting work he did for synthetic mesh companies such as C.R. Bard, Coloplast and Boston Scientific, the more than one thousand hours he spent developing instructional and marketing materials for prolapse mesh and incontinence products and the supervision and vetting of ongoing regulatory affairs as the president and Chief Operating Officer of multiple medical device companies and review of internal documents.

Conclusion

Dr. Zipper is qualified due to his long practice in urogynecology as well as his unique experience in acting as a product design consultant for his own company and numerous other pelvic mesh manufacturers; therefore, he is qualified to testify in these cases.

Dated: May 9, 2016

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 9th day of May 9, 20162016, this document was filed with the Clerk of Court using the Florida Courts E-Filing Portal system, which will serve a true and correct copy of the same, together with a notice of electronic filing, on all counsel of record. A copy has also been served on all counsel of record on the attached service list.

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